

1. EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - I
ANTIMICROBIAL PROGRAM BRANCH

IN 02-12-96 OUT 03-22-97
Bwa
Reviewed by Bruce H. Mann Date 03-22-97
LAN Code 68660-U.497 *Nicholas E. Griffin*
EPA Reg. No. or File Symbol 68660-U
EPA Petition or EUP No. None
Date Division Received 10-16-96
Type Product Sanitizer for (precleaned food contact surfaces)
MRID No (s) Data were submitted under MRID # 441380-06
Product Manager PM-32 (Brennis)
Product Name Proxitane AHC Liquid Sanitizer
Company Name Solvay Interlox
Submission Purpose A new application

Type Formulation A liquid concentrate to be diluted for use.

<u>Active Ingredient (s):</u>	<u>%</u>
Hydrogen peroxide	20.00
Peroxyacetic acid	5.50

202.0 Recommendations
202.0 Claims Related to Human Health
202.1 Efficacy Not Supported by the Data

- A. The submitted sanitizing data (for previously cleaned food contact surfaces) developed by the AOAC Germicidal and Detergent Sanitizer Method are not acceptable to support the product claim as a sanitizing rinse for food contact surfaces which have been thoroughly precleaned, rinsed with potable water and followed with the terminal sanitizing rinse.

In order to support a claim as a food contact surface sanitizing rinse, the data must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds.

202.3 Additional Information/Data Required to Support Efficacy

- A. To be satisfactory or valid, the concentration of product used to generate data must demonstrate a 99.999% reduction over the control numbers within 30 seconds. For guidance, refer to item 2 (ii) of DIS/TSS-4 enclosure and refer to the AOAC Germicidal and Detergent Sanitizing Test, and note performance standards the product must meet under results.

203.0 The subject product proposed label "proxitane AHC Liquid Sanitizer" cannot be reviewed until efficacy data requirements are met.
For required label use directions, refer to DIS/TSS-17 enclosure.

DIS/TSS-4 Jan. 30, 1979
EFFICACY DATA REQUIREMENTS

Sanitizing rinses (for previously cleaned food-contact surfaces).

Sanitizers applied to food contact surfaces are defined as incidental food additives under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 201 et seq.), and require establishment of a food additive tolerance. Recommendation of a potable water rinse after treatment does not preclude this requirement.

- (1) Halide chemical products. Efficacy of sanitizing rinses formulated with iodophors, mixed halides, and chlorine bearing chemicals must be substantiated with data derived from the AOAC Available Chlorine Germicidal Equivalent Concentration Method.
 - (i) Test requirements. Data from one test on each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against S. typhi are required.
 - (ii) Performance standard. Test results must show product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine. (The reference standard is sodium hypochlorite.)
- (2) Other chemical products. Efficacy of sanitizing rinses formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, and anionic detergent-acid formulations must be substantiated with data derived from the AOAC Germicidal and Detergent Sanitizers Method.
 - (i) Test requirements. Data from the test on one sample from each of 3 different batches, one of which is at least 60 days old, against both E. coli and S. aureus are required. When claims for the effectiveness of the product in hard water are made, all required data must be developed at the hard water tolerance claimed.
 - (ii) Performance standard. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and percentage reduction over the control. The minimum concentration of the product which provides the results required above is the minimum effective concentration.